# POTPOURRI
# Department of Environmental Quality
# Office of the Secretary

# RISK/COST/BENEFIT STATEMENT
# LABORATORY ACCREDITATION RULE (OS007)

[The following is an abbreviated version of the Risk/Cost/Benefit Statement prepared for the Joint Legislative Committee on the Budget, which consists of the main body of the statement but which excludes the attachments. The complete statement may be viewed or purchased at the Department of Environmental Quality, Investigations and Regulatory Development Division, Fourth Floor, 7290 Bluebonnet Road, Baton Rouge, LA. Additionally, the complete statement is available on the Internet at http://www.deq.state.la.us/olae/irdd/olaeregs.htm. Call (504) 765-0399 for additional information.]

## INTRODUCTION

The Louisiana Department of Environmental Quality is proposing the Laboratory Accreditation Rule (OS007). This rule seeks to establish a formal regulatory program to provide for accreditation of commercial environmental laboratories which produce environmental data pursuant to department regulations or permits or to the Environmental Quality Act (La.R.S. 30:2001 et seq.) This program is authorized under R.S. 30:2011(D)(22). This program will include commercial environmental laboratories in Louisiana and those outside the state which do business in Louisiana. The department roughly estimates this to be approximately 120 laboratories.

This statement is prepared to satisfy the requirements of R.S. 30:2019(D) and R.S. 49:953(G) (Acts 600 and 642 of the 1995 Louisiana Legislature, respectively). However, this document does not purport to be a scientific quantitative analysis of cost, risk, or economic benefit, although costs of implementation were quantified to the extent practical.

The department interprets the statutes above as allowing a qualitative analysis of economic and environmental benefit where a more quantitative analysis is not practicable and when the qualitative benefits outweigh the costs in a manner which is intuitively obvious. The statute allows the secretary to certify, based on qualitative benefits alone, that the benefits of a rule outweigh the costs.

This is the approach which is taken with this risk/cost/benefit statement. As discussed further in this document, the Laboratory Accreditation Rule provides indirect environmental and economic benefits by ensuring high quality laboratory data. Assessing dollar benefits of avoided environmental risk or economic benefits of this rule is not practicable. In addition, the department

asserts that the indirect and direct environmental and economic benefits to be derived from this rule will, in the judgment of reasonable persons, outweigh the costs associated with the implementation of the rule and that the rule is the most cost-effective alternative to achieve these benefits.

**RISKS ADDRESSED BY THE RULE**

Although the Laboratory Accreditation Rule does not address direct risks to human health or the environment, it does impact risk that indirectly can have great effects on human health and environment. Most regulatory programs of the department, such as the air, water, waste, and radiation programs rely principally on self-reported data from regulated entities to determine environmental violations, environmental contamination, human health and environmental risk, environmental contamination and damage, etc. Much of this self-reported information is laboratory data (e.g., discharge monitoring reports, air quality data, groundwater monitoring reports). It is absolutely essential to these programs that this laboratory data be sound. In addition, most facilities regulated by the department rely on third-party, commercial laboratories to produce part or all of their laboratory data which, in turn is submitted to the department. These facilities are ultimately responsible for the quality of this data. It is of the utmost importance that the department, the regulated community, and the public have confidence in environmental laboratory data.

This rule addresses the direct risks of: use of improper or inconsistent laboratory procedures and methods; use of faulty laboratory equipment; failure to properly maintain laboratory equipment; poor or fraudulent record keeping; improper QA/QC procedures or data; fraudulent laboratory data; fraudulent QA/QC data, employment of untrained or unqualified personnel, and finally the simple accumulation of minor procedural, equipment, or record keeping errors that lead to overall lower quality laboratory data.

These direct risks can lead to many indirect risks that may be of great consequence. For example, poor or fraudulent data can lead to under-reporting or over-reporting of environmental violations (e.g., incorrect NPDES Discharge Monitoring Reports). It can also cause underestimation or overestimation of the extent of contamination of a remediation site. Underestimation or overestimation of human exposure to toxic agents can result from incorrect laboratory sample results. Another example is liner construction for hazardous waste or solid waste disposal facilities (e.g., landfills). Incorrect or fraudulent sample results from QA/QC testing during liner construction can to lead to improper liner construction and ultimate liner failure.

Poor or fraudulent initial background groundwater sample results at a hazardous waste or solid waste disposal facility or at a remediation site can cause the subsequent groundwater monitoring program to be useless. Improper QA/QC procedures or data can render associated sample results as suspect or useless, even though they may in reality be accurate. Poor or fraudulent sample data generated during a permit application process (e.g., emission sources or wastewater discharges) may result in permit limits or conditions that are either overprotective or under protective of human health or the environment.

These or other risks can lead to increased risk to human health or the environment (e.g., leaking landfill liners, incomplete soil or groundwater cleanups, improper discharges or emissions to surface water or air, delayed or missed detection of significant groundwater contamination, etc.). On the other hand, these risks can lead to increased and unnecessary expense to regulated facilities (e.g., overtreatment of discharges or emissions due to overly protective permits, reinstallation or repair of improperly-installed liners, unnecessary cleanup of soils or groundwater, etc.).

**Laboratory Fraud**

Fraudulent activity, as stated earlier is one of the risks addressed by the rule. Although the extent of fraudulent activities in environmental laboratories in Louisiana is not known, fraud does occur. At least four recent cases of laboratory fraud are worth noting:

**State of Louisiana vs. Laboratory A**

In August, 1992, a chemical manufacturing company in St. Gabriel, Louisiana, pleaded no contest to charges of producing fraudulent laboratory QA/QC data in their in-house laboratory and agreed to pay a $250,000 fine and $50,000 each to the Iberville Parish Drug Task Force and the East Baton Rouge-Pointe Coupee Drug Task Force. In addition, the company terminated the employment of seven laboratory employees and demoted the laboratory manager to a non-supervisory level.

In this case, the involved employees logged false spike and blank sample results (associated with the NPDES and LWPDS permits) over at least a two-year period. Apparently, the data reported on the facility's discharge monitoring reports were not affected.

**United States vs. Laboratory B**

In January, 1991, charges of submission of false claims were filed against a commercial laboratory in Baton Rouge, Louisiana, by the U.S. Attorney's office. The company pleaded guilty and agreed to pay a $500,000 fine. This commercial lab was performing work on EPA contract.

In this case, two laboratory employees admitted to falsifying laboratory sample results on the instructions of the laboratory manager.

**United States vs. Laboratory C**

In April, 1992, three employees of a commercial laboratory in St. Rose, Louisiana, pleaded guilty to conspiracy to submit false claims. Two were fined $500 and sentenced to two years probation; one was fined $250 and sentenced to two years probation. This commercial lab was performing superfund work on contract with EPA.

In this case, the three employees intentionally failed to calibrate a GC/MS

instrument and manually overrode the automatic features of the instrument in order to obtain false analytical results, which were ultimately submitted to EPA.

**United States vs. Laboratory D**

In July, 1995, the Vice President/Manager of a commercial laboratory in Lafayette, Louisiana, pleaded guilty to falsification of laboratory data. In a pretrial diversion agreement, charges against the company were deferred for two years based on the company meeting certain conditions, including submitting to independent lab audits. This commercial laboratory was performing NPDES discharge analysis for oil production companies and publicly-owned treatment works.

In the case, the defendant, who was both vice president of the company and manager of the laboratory, was altering lab results which were obtained by lab technicians, fabricating lab data where no analysis was performed, and directing lab technicians to falsify lab results.

## ENVIRONMENTAL AND PUBLIC HEALTH BENEFITS

Although environmental and public health benefits of the rule are not to be quantified in this statement, on a qualitative basis the benefits are self-evident. This rule will address the direct and indirect risks discussed earlier and produce significant environmental and public health benefits.

Specifically, through a reasonable program of accreditation, self-reporting, performance sampling, and third-party audit inspections, this program will significantly reduce the frequency of laboratory errors and fraudulent results, and will maintain and increase confidence of regulators, customers, and the public in commercial environmental laboratory data. The accreditation program will also help to level the highly competitive playing field among commercial laboratories in the state. The program will provide a means of overseeing out-of-state laboratories which provide services to Louisiana customers. It will also allow accredited in-state laboratories to receive reciprocal accreditation from other states in order to provide analyses to customers in those states. Reciprocal accreditation from multiple states allows laboratories to avoided applying for accreditation in every state, thereby lowering their operating costs.

In directly reducing the frequency of errors and fraudulent results, the laboratory accreditation program will also yield indirect benefits. Improved monitoring and enforcement of emission, discharge, and disposal regulations and permits should result from better laboratory data. Further, the accreditation program can be expected to reduce the indirect environmental and human health risks, some of which were listed in the previous section. Better laboratory data is a double-edged sword. It makes catching violators easier, but it also may result in fewer regulated entities being unfairly penalized. Also, assessment and remediation of contaminated sites becomes a more precise, fair, and environmentally-protective process with good laboratory data.

## ESTIMATED SOCIAL AND ECONOMIC COSTS

### Implementation Costs to Regulated Community

Costs to the regulated community of complying with the rule were estimated by surveying a sample of affected laboratories. It should be noted that these costs were strictly based on these laboratory survey responses which were interpreted using best agency judgement. There is the strong possibility that these figures overstate actual implementation costs to some degree because many laboratories in the state already meet all or part of the rule requirements and will incur lower implementation costs. However, to what degree this is true is not easy to quantify.

Surveys were sent to 43 laboratories within the state. Completed surveys were returned by 19 environmental laboratories. These survey results were averaged to obtain a per-laboratory cost to implement the rule. The average costs per laboratory were as follows:

| | |
|---|---|
| First Year Costs Per Lab | $38,412 |
| Second Year Costs Per Lab | $26,777 |
| Third Year Costs Per Lab | $21,215 |
| Total Costs Per Lab | $86,404 |

These costs do not include fees charged by the department. These per-laboratory costs were multiplied by 120 environmental laboratories to determine a total cost to the regulated community for implementing the rule. These total costs were, as follows:

| | |
|---|---|
| Total First Year Cost | $ 4,609,440 |
| Total Second Year Cost | $ 3,213,240 |
| Total Third Year Cost | $ 2,545,800 |
| Total Three-Year Cost | $10,368,480 |

### Fee Costs to Regulated Community

Under the rule, each laboratory must submit a $500 accreditation fee once every three years. In addition, each laboratory must submit an annual fee which ranges from $250 to $2500 depending on the size and complexity of the laboratory. To estimate costs to the regulated community due to fees, it was assumed that each laboratory would pay an average annual fee equal to the midpoint between the minimum and maximum annual fees, or $1375 per year. Using the figure of 120 laboratories, the following costs due to fees were estimated:

| | |
|---|---|
| Total First Year Accreditation Fees | $ 60,000 |
| Total First Year Annual Fees | $165,000 |
| Total Second Year Annual Fees | $165,000 |
| Total Third Year Annual Fees | $165,000 |
| Total Three-Year Fees | $555,000 |

### Audit Costs to the Regulated Community

The rule requires that each laboratory must undergo an independent third-party audit once every three years. Based on telephone inquiries, audits by private auditors are assumed to range in cost from $500 to $750 per day and last from 2.5 to 3.5 days. Averaging these figures gives an average per day cost of $625 and average audit duration of 3 days. Based on this, the average audit can be assumed to cost $1875. Using the figure of 120 laboratories, the following costs due to audit expenses were estimated:

| | |
|---|---|
| Total First Year Audit Expenses | $ 75,000 |
| Total Second Year Audit Expenses | $ 75,000 |
| Total Third Year Audit Expenses | $ 75,000 |
| Total Three-Year Audit Expenses | $225,000 |

**Total Costs to Regulated Community**

Therefore, the total costs to the regulated community over three years can be estimated by totaling compliance costs, audit costs, and fee costs, as follows:

| | Implementation | Fees | Audit Expense | Total |
|---|---|---|---|---|
| First Year Costs | $ 4,609,440 | $225,000 | $ 75,000 | $ 4,909,440 |
| Second Year Costs | $ 3,213,240 | $165,000 | $ 75,000 | $ 3,453,240 |
| Third Year Costs | $ 2,545,800 | $165,000 | $ 75,000 | $ 2,785,800 |
| Total Three-Year Costs | $10,368,480 | $555,000 | $225,000 | $11,148,480 |

**Agency Costs**

Agency Costs were estimated by totaling personnel, equipment, and supply costs for the number of new department personnel that would be needed to implement the rule. The new personnel identified were, as follows:

Environmental Quality Coordinator
Environmental Chemist 3
Environmental Chemist 2
Environmental Program Analyst 1
Word Processor Operator 1

Costs for these personnel were estimated using midpoint salaries plus related benefits, and using generic equipment, supply, travel, and telephone costs. These were estimated, as follows:

| | |
|---|---|
| Total First Year Agency Cost | $187,944 |
| Total Second Year Agency Cost | $188,489 |
| Total Third Year Agency Cost | $194,969 |
| Total Three-Year Agency Cost | $571,402 |

It should be noted that above agency costs do not represent additional costs of implementing the rule, as these agency costs will be borne by the user fees which were previously

counted.

**Total Cost of Implementation**

The total estimated cost of implementing the rule over the first three years is $11,148,480, which yields an average annual cost of approximately $3,716,160.

## CONCLUSION

The department understands that there are significant costs associated with the implementation of the Laboratory Accreditation Rule. However, as described in this document, the department believes that the benefits of avoided environmental and public health risk, as well as other benefits, significantly outweigh the costs of implementation of the rule in a manner that is intuitively obvious.

J. DALE GIVENS
Secretary